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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,202	01/19/2000	Guy LaTorre	028870-057	4074

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[REDACTED] EXAMINER

BENNETT, RACHEL M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 01/25/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/488,202	LATORRE ET AL.
Examiner	Art Unit	
Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 November 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z3</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Supplemental IDS and Response with Attachment filed 11/21/01.

Claims 1-18 are pending.

Specification

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 18 are indefinite because applicant does not clearly define "other cosmetically useful additives" in the claims. Clarification is requested.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) in further view of Bonfield *et al.* (US Pat. No. 5,728,753).

Witbeck discloses a process and composition for strengthening nails, especially human fingernails. The said composition consists of a hydrophilic polymer, dispersed in an aqueous

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solution with a fragrance (see Reference claim 3 and column 2, lines 34-37). Witbeck does not teach bioactive glass as part of the composition.

Bonfield is relied on for the teaching of particulate bioactive glass in a composition that is able to achieve attachment to soft and hard tissue by formation of a layer of hydroxyapatite from said bioactive glass material that increases the presented area and enhances formation of a biological layer (see claim 1, column 1 lines 65-67 and column 2, lines 16-41). Bonfield also teaches average particle size of bioactive glass ranging from about 0.5 um to about 500 um (see Reference claim 1).

It is the position of the examiner that it would be obvious to one of ordinary skill in this art at the time of the invention to use the teachings of Bonfield with regard to using bioactive glass as a component in a composition to repair soft and hard tissue in the teaching of Witbeck because Bonfield teaches that damaged nails can be strengthened and repaired by adding a composition for an extended period of time as in Witbeck. The addition of Bonfield to Witbeck further enhances the ability of Witbeck's composition to strengthen and treat nails. The expected result would be a method for treating nails by applying a composition comprising of particles of bioactive glass, an aqueous solvent, a hydrophilic polymer and a fragrance for an extended period of time.

5. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Zook (US Pat. No. 5,181,914).

Witbeck and Bonfield as disclosed above teach a composition for treating nails. Witbeck and Bonfield do not teach a medicating device for application to nails comprising a

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viscoelastic gel pad. Zook is relied on for the teaching of a medicating device for human nails and adjacent tissues wherein the said gel pad is perfused with one or more pharmacologically active agents (see claims 1 and 9).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teachings of Zook with regards to perfusing pharmacologically active agents into a medicating device, specifically a viscoelastic gel pad in Wibeck and Bonfield because Zook teaches the use of pharmacologically active agents to help strengthen and treat nails and adjacent tissue as in Wibeck and Bonfield. The expected result would be a medicating device for application to the nails comprising a viscoelastic gel pad perfused with bioactive glass and other pharmacologically active components.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Shepherd *et al.* (US Pat. No. 3,914,405).

Witbeck and Bonfield as disclosed above teach a method for treating nails and adjacent tissues. Witbeck and Bonfield do not teach the method for removing such a composition. Shepherd is relied on for the teaching of a method to remove nail compositions by simply washing the hands in water (see column 6, lines 38-45).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teaching of Shepherd with regard to a method of removing a nail composition by washing with water in the teachings of Witbeck and Bonfield because Shepherd teaches a composition for nails with the expectation of removal from nail after an extended period of time as in Shepherd. The

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expected result would be a composition for nails and soft tissue with a method of removal by way of simply washing the nails in water.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of LeGrow (US Pat. No. 5,403,402).

Witbeck and Bonfield as disclosed above teach a composition for treating nails. Witbeck and Bonfield do not teach the method of applying a protective lacquer coating on the nails following the removal of the composition. LeGrow is relied on for the teaching of removing traces of prior nail lacquer coatings or residues from soap and hand creams, before a new nail lacquer is applied to nails (see column 2, lines 32-35).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teachings of LeGrow with regards to removing all residues and coatings from the nails before applying a new nail lacquer in Wibeck and Bonfield because LeGrow teaches the application of a composition to nails with the expectation of having the composition contact a clean surface in order to achieve the goal of coating as in Winbeck and Bonfield. The expected result would be the method of applying a protective lacquer coating on the nails following removal of the composition.

Response to Arguments

8. Applicant's arguments filed 11/21/01 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus, claim **Claims 1-8, 14-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) in further view of Bonfield *et al.* (US Pat. No. 5,728,753), **Claims 11-13** are rejected under 35

U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Zook (US Pat. No. 5,181,914), **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Shepherd *et al.* (US Pat. No. 3,914,405) and **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of LeGrow (US Pat. No. 5,403,402).

Applicants argue neither Witbeck or Bonfield disclose the nail enhancing ability of bioactive glass discovered by the present inventor. However, the examiner relies on the teaching of Witbeck disclosing a composition for strengthening nails while Bonfield discloses bioglass suitable for use for attachment to soft and hard tissue. It is the position of the examiner that soft and hard tissues disclosed in Bonfield (see col. 2 lines 49-58) are recognized by the art to include nails. Therefore, it would have been obvious to one of ordinary skill in the art to modify the teachings of Bonfield with regard to using bioactive glass as a component in a composition to repair soft and hard tissue in the teaching of Witbeck because Bonfield teaches that damaged nails can be strengthened and repaired by adding a composition for an extended period of time as in Witbeck. The addition of Bonfield to Witbeck further enhances the ability of Witbeck's composition to strengthen and treat nails. The expected result would be a method for treating nails by applying a composition comprising of particles of bioactive glass, an aqueous solvent, a hydrophilic polymer and a fragrance for an extended period of time.

9. The Declaration under 37 CFR 1.132 filed 7/9/01 is insufficient to overcome the rejection of claims 1-18 based upon Bonfield (US 5728753) and Witbeck (US 5508027) as set forth in the

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last Office action because: it appears from Leg #1, Leg #2 and Leg #3, the critical parameters which determine the HA precipitation are not cited in the instant claims. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. It also include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. The declaration is not persuasive because the reference uses the same bioglass and teaches the same advantages. Therefore, advantages observed by applicants are to be expected, not unexpected.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R.Bennett: RMB
January 18, 2002

THURMAN K. PAGE
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TK Page